

PATENT
Attorney Docket No. 0190.00

REMARKS

This is a full and timely response to the final Office Action mailed June 14, 2007. Reconsideration of the application and allowance of presently pending claims as amended, are respectfully requested.

A. Present Status of Patent Application

Independent claims 1, 23 and 63 have been directly amended, and the remaining claims indirectly amended as they depend from one of the amended Independent claims. Claims 21-22, 26-27, 32-33, 41-62 and 79-96 have been cancelled without prejudice, waiver or estoppel. Claim 97 (originally misnumbered as 98) had been previously withdrawn pursuant to a Restriction Requirement. Claims 1-20, 23-25, 28-31, 34-40, and 63-78 remain pending.

B. Response to Rejections

1. Provisional Double Patenting Rejection

The provisional rejection of claims 1-16, 18-20, 23-36, 38-40, 43-72, and 74-76 on the ground of nonstatutory obviousness-type double patenting over the claims of co-pending U.S. application 11/187,757 has been noted. Should the provisional rejection mature into a double-patenting rejection which is the sole ground of rejecting the present claims, consideration will be given to filing the appropriate terminal disclaimer.

2. Rejection under 35 U.S.C. §112

Claims 1-96 were rejected under 35 U.S.C. §112 as allegedly non-enabling. This rejection is respectfully traversed as to the pending claims.

Initially, it is to be noted that enablement is found even if a reasonable amount of routine experimentation is required. *Enzo Biochem Inc v Calgene Inc*, 52 USPQ 2d 1129 (Fed Cir 1999.) Moreover, the *In re Wand* factors are not to be construed as an absolute requirement; not all of the factors need be reviewed when determining whether a disclosure is enabling. *Id.*

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While applicant contends that even the un-amended claims are clear and satisfy 35 U.S.C. §112, Applicant has amended claims 1, 23 and 63 to further clarify the method. In this regard, for purposes of §112, the claimed method is one of: "administering directly to the lungs by inhalation, a formulation "having efficacy against said [specific] pulmonary fungal growth"...Thus the treatment is properly the administration of the formulation, to any patient in need of such treatment. Such a claim is absolutely definite and certain.

Moreover, one skilled in the art would readily be able to perform the steps of: (1) ascertaining the type of fungal infection existing in a patient (or the type of pulmonary fungal infection to which a given patient would be most susceptible, given the patient's condition; (2) selecting an antifungal known to be efficacious against said infection; and (3) selecting a dose and regimen to treat said infection.

3. Rejections under 35 U.S.C. §102(e) over Tarara et al

Claims 1-7, 11-21, 23-29, 33-41, 43 and 45-53 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Tarara et al US 2006/0159625. This rejection is respectfully traversed as to the pending claims.

Tarara's teaching is incomplete regard to applicants' claimed method of administration, in particular with respect to the administration of the powder formulation in a first dosage, followed after a predetermined time interval, by a second dosage, and wherein the first dosage is greater than the second dosage.

As stated in the present application, at paragraph 0034:

A therapeutic method according to the present invention takes advantage of the lung retention and concentration properties of the pharmaceutical formulation of the present invention to effectively treat a pulmonary fungal infection and/or to provide prophylaxis against a pulmonary fungal infection.

Applicants contend that the Tarara reference does not teach or suggest such a method as claimed.

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4. Rejection under 35 U.S.C. §103 over Tarara et al

Claims 8-10, 30-32, and 44 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Tarara et al US 2006/0159625. This rejection is respectfully traversed as to the pending claims.

According to MPEP 706.02(1)(2), a reference cannot be used to support a §103(a) rejection against pending claims in an application if the reference and application were commonly owned or subject to an obligation of assignment to the same person or organization at the time the invention of the pending claims was made.

Applicants hereby establish common ownership or, an obligation for assignment to, the same person or organization by stating that the present application (U.S. Patent Application No. 10/751,342) and the reference (U.S. Patent Application No. 2006/0159625 to Tarara et al) were, at the time of the presently claimed invention of U.S. Patent Application No. 10/751,342, commonly owned. Hence, the Tarara et al reference cannot be used in a rejection under 35 U.S.C. §103(a) against the pending claims of the present application. As such, it is respectfully requested that the §103(a) rejection of claims 8-10, 30-32 and 44 be withdrawn.

5. Rejection under 35 U.S.C. §103(a) over Ponikau et al.

Claims, 1-15, 23-35, and 43-52 were rejected under 35 USC 103 (a) as allegedly anticipated by *Ponikau et al*, US 6207703.

Applicants respectfully ask the Examiner to reconsider this overbroad presumption in view of the following.

Ponikau et al. is limited to teaching an methods and materials for treating a **non-invasive** fungus induced rhinosinusits, and has nothing to do with pulmonary fungus or pulmonary delivery and in particular does not teach or suggest methods and formulations comprising powders for pulmonary delivery. As such *Ponikau et al.* does not teach or suggest the elements of applicants' amended claims, in particular the features of pulmonary delivery of an antifungal powder specific for a predetermined pulmonary infection, and wherein an administration protocol, as claimed in Independent claims 1 and 23, is used.

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As reiterated by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, S. Ct. 1727 (2007); 82 USPQ2d 1385, 1397 (2007), the factors stated in *Graham v. John Deere*, 383, U.S. 1, 148 USPQ 459 (1966) still control an obviousness inquiry. That is to say, the considerations which must be followed in an inquiry directed to the obviousness or non-obviousness of an invention are as follows:

- i. The claimed invention must be considered as a whole;
- ii. The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; and
- iii. The references must be viewed without the benefit of hindsight afforded by the claimed invention or accompanying specification.

In conducting the above analysis, one must consider the level of ordinary skill in the art at the time of the invention, as well as whether there exists a reasonable expectation of success.

Additionally, as to the rejection of the dependent claims 2-15, 24-25 and 28-31, as the independent claims are allowable over the prior art of record, then their dependent claims are allowable as a matter of law, because these dependent claims contain all features/elements/steps of their respective independent claim. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Additionally and notwithstanding the foregoing reasons for the allowability of independent claims 1, and 23, the dependent claims recite further features/steps and/or combinations of features/steps (as is apparent by examination of the claims themselves) that are patentably distinct from the prior art of record. Hence, there are other reasons why these dependent claims are allowable.

6. Rejection under 35 U.S.C. §103(a) over *Ponikau et al.* in view of *Weickert et al.*

Claims 16, 20, 36, 40 and 53 were rejected under 35 USC 103 (a) as allegedly anticipated by *Ponikau et al.* in view of *Weickert et al.*, US 2002/0177562.

Applicants respectfully traverse this rejection for the following reasons. Each of the rejected claims are dependent claims, and for reasons advanced in paragraph 5 above, the Independent claims are allowable over the cited reference(s), then their dependent claims are allowable as well. See *In re Fine* (supra.)

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Thus, *Ponikau et al.* does not teach or suggest the features of Independent claims 1 or 23, nor do the references individually, or the combination thereof teach the subject matter of dependent claims 16, 20, 36 or 40 (claim 53 being cancelled.)

Weickert et al. can not be used to augment the deficiencies in *Ponikau et al.* According to MPEP 706.02(1)(2), a reference cannot be used to support a §103(a) rejection against pending claims in an application if the reference and application were commonly owned or subject to an obligation of assignment to the same person or organization at the time the invention of the pending claims was made.

Applicants hereby establish common ownership or, an obligation for assignment to, the same person or organization by stating that the present application (U.S. Patent Application No. 10/751,342) and the reference (U.S. Patent Application No. 2002/0177562 to *Weickert et al.*) were, at the time of the presently claimed invention of U.S. Patent Application No. 10/751,342, commonly owned. The assignee of record on the *Weickert et al.* application is Inhale Therapeutics, the former corporate name for Nektar Therapeutics (as the same entity). As such, it is respectfully requested that the §103(a) rejection of claims 16, 20, 36, 40 and 53 be withdrawn.

7. Rejections under 35 U.S.C. §103(a) over *Ponikau et al.* in view of *Unger*, *Ponikau et al.* in view of *Johnson*; and *Ponikau et al.* in view of *Lloyd et al.*

Claims 17-19 and 37-39 were rejected under 35 USC 103 (a) as allegedly anticipated by *Ponikau et al.* in view of *Unger*, US 2001/0018072. Claims 21 and 41 were rejected under 35 USC 103 (a) as allegedly anticipated by *Ponikau et al.* in view of *Johnson*, US 5,126,123. Claims 22 and 42 were rejected under 35 USC 103 (a) as allegedly anticipated by *Ponikau et al.* in view of *Lloyd*, US 5,544,646.

Claims 21-22 and 41-42 have been cancelled, thus the rejection thereto is moot.

Applicants respectfully traverse the rejection of the remaining for the same reasons advanced in paragraphs 5-6 above. The combination of *Ponikau et al.* with any one or more of *Unger*, *Johnson et al.* and/or *Lloyd* does not change this conclusion.

Unger teaches non-specifically delivery of active agents to a patient's lungs, a concept which is old in the art. *Unger*, either alone, or combined with *Ponikau et al.*, does not teach, suggest or disclose applicants specifically claimed method of treating

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and/or preventing pulmonary infections, including administering in the claimed dosage and regimen. Johnson simply discloses the use of certain soluble surfactants to stabilize a micronised drug for inhalation via a metered dose inhaler. Such devices are well known, and require a propellant to deliver a drug to the lungs. This reference, however, does not address the problem solved by applicant, that is, a method for treating a pulmonary fungal infection. Similarly, Lloyd does not teach or suggest applicants' claimed methods of treating a pulmonary fungal infection. Instead, Lloyd is directed to a disposable device for containing and delivering liquid medicaments, which are **capable** of being inhaled.

Applicants note that no art rejection was made in respect of pending Claims 63-78. As the rejections thereof under §112, and double patenting, have been addressed above, accordingly applicant respectfully contends these claims are in condition for allowance, and such action is respectfully requested.

CONCLUSION

In view of the foregoing, applicants submit that pending claims 1-20, 23-25, 28-31, 34-40, and 63-78, satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all rejections is respectfully requested and a prompt mailing of a Notice of Allowance is solicited.

Please grant any extensions of time required to enter this response and charge any additional required fees to deposit account 50-0348.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 620-5318.

Respectfully submitted,

Date: _____

11/13/07

By: _____

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